

PATENT COOPERATION TREATY

From the INTERNATIONAL SEARCHING AUTHORITY

PCT

To:
Smolenski, Jr....
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**SUNSTEIN
KANN, MURPHY & TIMBERS LLP
RECEIVED**

FEB 28 2011

NOTIFICATION OF TRANSMITTAL OF
THE INTERNATIONAL SEARCH REPORT AND
THE WRITTEN OPINION OF THE INTERNATIONAL
SEARCHING AUTHORITY, OR THE DECLARATION

(PCT Rule 44.1)

Applicant's or agent's file reference 2960/A17WO	Date of mailing (day/month/year) 7 January 2011 (07-01-2011)
International application No. PCT/US2010/046868	International filing date (day/month/year) 26 August 2010 (26-08-2010)
Applicant CONFORMIS, INC.	

1. ☒ The applicant is hereby notified that the international search report and the written opinion of the International Searching Authority have been established and are transmitted herewith.

Filing of amendments and statement under Article 19:

The applicant is entitled, if he so wishes, to amend the claims of the International Application (see Rule 46):

When? The time limit for filing such amendments is normally two months from the date of transmittal of the International Search Report.

Where? Directly to the International Bureau of WIPO, 34 chemin des Colombettes
1211 Geneva 20, Switzerland, Facsimile No.: (41-22) 338.82.70

For more detailed instructions, see *PCT Applicant's Guide*, International Phase, paragraphs 9.004 - 9.011.

2. ☐ The applicant is hereby notified that no international search report will be established and that the declaration under Article 17(2)(a) to that effect and the written opinion of the International Searching Authority are transmitted herewith.

3. ☐ **With regard to any protest** against payment of (an) additional fee(s) under Rule 40.2, the applicant is notified that:

- ☐ the protest together with the decision thereon has been transmitted to the International Bureau together with the applicant's request to forward the texts of both the protest and the decision thereon to the designated Offices.
- ☐ no decision has been made yet on the protest; the applicant will be notified as soon as a decision is made.

4. **Reminders**


The applicant may submit comments on an informal basis on the written opinion of the International Searching Authority to the International Bureau. The International Bureau will send a copy of such comments to all designated Offices unless an international preliminary examination report has been or is to be established. Following the expiration of 30 months from the priority date, these comments will also be made available to the public.

Shortly after the expiration of **18 months** from the priority date, the international application will be published by the International Bureau. If the applicant wishes to avoid or postpone publication, a notice of withdrawal of the international application, or of the priority claim, must reach the International Bureau before completion of the technical preparations for international publication (Rules 90bis.1 and 90bis.3).

Within **19 months** from the priority date, but only in respect of some designated Offices, a demand for international preliminary examination must be filed if the applicant wishes to postpone the entry into the national phase **until 30 months** from the priority date (in some Offices even later); otherwise, the applicant must, **within 20 months** from the priority date, perform the prescribed acts for entry into the national phase before those designated Offices.

In respect of other designated Offices, the time limit of **30 months** (or later) will apply even if no demand is filed within 19 months.

For details about the applicable time limits, Office by Office, see www.wipo.int/pct/en/texts/time_limits.html and the *PCT Applicant's Guide*, National Chapters.

Name and mailing address of the International Searching Authority  European Patent Office, P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk Tel. (+31-70) 340-2040 Fax: (+31-70) 340-3016	Authorized officer ULLRICH, Josef Tel: +49 (0)89 2399-8048
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PATENT COOPERATION TREATY

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference 2960/A17WO	FOR FURTHER ACTION see Form PCT/ISA/220 as well as, where applicable, item 5 below.	
International application No. PCT/US2010/046868	International filing date (day/month/year) 26/08/2010	(Earliest) Priority Date (day/month/year) 26/08/2009
Applicant CONFORMIS, INC.		

This international search report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This international search report consists of a total of 5 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

a. With regard to the **language**, the international search was carried out on the basis of:

- ☒ the international application in the language in which it was filed
☐ a translation of the international application into _____, which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1(b))

b. ☐ This international search report has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43.6bis(a)).

c. ☐ With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, see Box No. I.

2. ☐ **Certain claims were found unsearchable** (See Box No. II)

3. ☐ **Unity of invention is lacking** (see Box No. III)

4. With regard to the **title**,

- ☒ the text is approved as submitted by the applicant
☐ the text has been established by this Authority to read as follows:

5. With regard to the **abstract**,

- ☐ the text is approved as submitted by the applicant
☒ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box No. IV. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority

6. With regard to the **drawings**,

- a. the figure of the **drawings** to be published with the abstract is Figure No. Ex10-1AB
☐ as suggested by the applicant
☐ as selected by this Authority, because the applicant failed to suggest a figure
☒ as selected by this Authority, because this figure better characterizes the invention
b. ☐ none of the figures is to be published with the abstract

INTERNATIONAL SEARCH REPORT

International application No.

PCT/US2010/046868

Box No. IV Text of the abstract (Continuation of item 5 of the first sheet)

A patient-specific knee implant 10 includes a femoral component 20 and a tibial tray component 30, and it is designed based on patient-specific data. An inner, bone-facing surface 40 of the femoral component 20 conforms to the corresponding surface of the femoral condyle. Alternatively, it can conform to one or more optimized bone cuts on the femoral condyle. However, the outer, articular surface 50 of the component 20 is enhanced to incorporate a smooth surface having a nearly constant radius in the coronal plane. The corresponding articular surface 70 of the tibial tray 30 has a surface contour in the coronal plane that is matched to the outer articular surface 50. In certain embodiments, the articular surface 50 of the component 20 incorporates a sagittal curvature that positively-matches the patient's existing or healthy sagittal radius.

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/046868

A. CLASSIFICATION OF SUBJECT MATTER
INV. A61F2/38
ADD.

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
A61F

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 2008/172125 A1 (EK STEVEN W [US]) 17 July 2008 (2008-07-17) paragraphs [0014] - [0029]	1-44
E	WO 2010/099231 A2 (CONFORMIS INC [US]; STEINES DANIEL [US]; ZHURAVLEV ALEXEY [US]) 2 September 2010 (2010-09-02)	1-44
L	paragraphs [0072] - [0076]	1-44
A	WO 2005/051240 A1 (CONFORMIS INC [US]; BURDULIS JR ALBERT G [US]; FITZ WOLFGANG [US]; LAN) 9 June 2005 (2005-06-09)	1-44
A	paragraphs [0068] - [0142]	
	US 2007/118055 A1 (MCCOMBS DANIEL L [US]) 24 May 2007 (2007-05-24) paragraph [0035]	1-44
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☒ Further documents are listed in the continuation of Box C.

☒ See patent family annex.

* Special categories of cited documents :

- *A* document defining the general state of the art which is not considered to be of particular relevance
- *E* earlier document but published on or after the international filing date
- *L* document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- *O* document referring to an oral disclosure, use, exhibition or other means
- *P* document published prior to the international filing date but later than the priority date claimed

- *T* later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- *X* document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- *Y* document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- * & * document member of the same patent family

Date of the actual completion of the international search

9 December 2010

Date of mailing of the international search report

07/01/2011

Name and mailing address of the ISA/
European Patent Office, P.B. 5818 Patentlaan 2
NL - 2280 HV Rijswijk
Tel. (+31-70) 340-2040,
Fax: (+31-70) 340-3016

Authorized officer

Buchmann, Gerhard

INTERNATIONAL SEARCH REPORT

International application No
PCT/US2010/046868

C(Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	US 2007/100462 A1 (LANG PHILIPP [US] ET AL) 3 May 2007 (2007-05-03) paragraphs [0165] - [0173] -----	1-44

INTERNATIONAL SEARCH REPORT

Information on patent family members

International application No

PCT/US2010/046868

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
US 2008172125	A1	17-07-2008	NONE
WO 2010099231	A2	02-09-2010	NONE
WO 2005051240	A1	09-06-2005	AU 2004293104 A1 09-06-2005 CA 2546965 A1 09-06-2005 EP 1686931 A1 09-08-2006 JP 2007514470 T 07-06-2007
US 2007118055	A1	24-05-2007	NONE
US 2007100462	A1	03-05-2007	AU 2006297137 A1 12-04-2007 CA 2623834 A1 12-04-2007 EP 1928359 A2 11-06-2008 JP 2009513187 T 02-04-2009 WO 2007041375 A2 12-04-2007

PATENT COOPERATION TREATY

From the
INTERNATIONAL SEARCHING AUTHORITY

To:		<h1>PCT</h1> <p>WRITTEN OPINION OF THE INTERNATIONAL SEARCHING AUTHORITY (PCT Rule 43bis.1)</p>	
see form PCT/ISA/220			
		Date of mailing (day/month/year) see form PCT/ISA/210 (second sheet)	
Applicant's or agent's file reference see form PCT/ISA/220		FOR FURTHER ACTION See paragraph 2 below	
International application No. PCT/US2010/046868	International filing date (day/month/year) 26.08.2010	Priority date (day/month/year) 26.08.2009	
International Patent Classification (IPC) or both national classification and IPC INV. A61F2/38			
Applicant CONFORMIS, INC.			

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☐ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step and industrial applicability; citations and explanations supporting such statement
- ☒ Box No. VI Certain documents cited
- ☒ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application


2. FURTHER ACTION

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA") except that this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of 3 months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Fax: +49 89 2399 - 4465	Date of completion of this opinion see form PCT/ISA/210	Authorized Officer Buchmann, Gerhard Telephone No. +49 89 2399-2288
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**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/046868

Box No. I Basis of the opinion

1. With regard to the **language**, this opinion has been established on the basis of:
 - ☒ the international application in the language in which it was filed
 - ☐ a translation of the international application into , which is the language of a translation furnished for the purposes of international search (Rules 12.3(a) and 23.1 (b)).
2. ☐ This opinion has been established taking into account the **rectification of an obvious mistake** authorized by or notified to this Authority under Rule 91 (Rule 43bis.1(a))
3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, this opinion has been established on the basis of a sequence listing filed or furnished:
 - a. (means)
 - ☐ on paper
 - ☐ in electronic form
 - b. (time)
 - ☐ in the international application as filed
 - ☐ together with the international application in electronic form
 - ☐ subsequently to this Authority for the purposes of search
4. ☐ In addition, in the case that more than one version or copy of a sequence listing has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
5. Additional comments:

Box No. II Priority

1. ☒ The validity of the priority claim has not been considered because the International Searching Authority does not have in its possession a copy of the earlier application whose priority has been claimed or, where required, a translation of that earlier application. This opinion has nevertheless been established on the assumption that the relevant date (Rules 43bis.1 and 64.1) is the claimed priority date.
2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43bis.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.
3. Additional observations, if necessary:

**WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING AUTHORITY**

International application No.
PCT/US2010/046868

Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims	
	No: Claims	<u>1-44</u>
Inventive step (IS)	Yes: Claims	
	No: Claims	<u>1-44</u>
Industrial applicability (IA)	Yes: Claims	<u>1-44</u>
	No: Claims	

2. Citations and explanations

see separate sheet

Box No. VI Certain documents cited

1. Certain published documents (Rules 43bis.1 and 70.10)

and /or

2. Non-written disclosures (Rules 43bis.1 and 70.9)

see form 210

Box No. VII Certain defects in the international application

The following defects in the form or contents of the international application have been noted:

see separate sheet

Re Item V

Reasoned statement with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

Reference is made to the following documents:

D1 US 2008/172125 A1 (EK STEVEN W [US]) 17 July 2008 (2008-07-17)

The present application does not meet the criteria of Article 33(2) PCT, because the subject-matter of claims 1, 23, and 35 is not new.

Document D1 discloses (see para 14-29) a patient-specific femoral implant for implantation on a portion of a femur of a patient's knee, comprising:

- a condylar portion (40) having a bone-facing surface (44) and an articular surface (42);
- the articular surface having a patient-specific curvature generally disposed in a first plane (AP curvature), the patient-specific curvature substantially replicating a corresponding curvature of at least a portion of the patient's condyle; the AP curvature of D1 is defined by several contact points (50a, 50b, 52a, 52b);
- the articular surface having a constant curvature in a second plane (ML curvature) that is generally transverse to the first plane: The ML curvature is defined by only two contact points (54a, 54b).

Therefore, the subject-matter of claims 1, 23 and 35 is already known from document D1.

Dependent claims 2-22, 24-34 and 36-44 do not contain any features which, in combination with the features of any claim to which they refer, meet the requirements of the PCT in respect of novelty and/or inventive step, see D1.

Re Item VI

Certain documents cited

Application No Patent No	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (<i>valid claim</i>) (day/month/year)
WO 2010/099231	02. Sept. 2010	24. Feb. 2010	24. Feb. 2009

Re Item VII

Certain defects in the international application

The independent claims are not written in the two part form (Rule 6.3(b) PCT), which in the present case would be appropriate, with those features known in combination from the prior art being placed in the preamble (Rule 6.3(b)(i) PCT) and with the remaining features being included in the characterising part (Rule 6.3(b)(ii) PCT).

The features of the claims are not provided with reference signs placed in parentheses to increase the intelligibility of the claims (Rule 6.2(b) PCT). This applies to both the preamble and characterising portion (see the PCT Guidelines 5.05).

The document D1 is not identified in the description and the relevant background art disclosed therein is not discussed (Rule 5.1(a)(ii) PCT).

The paragraph 309 refers in an unclear way to the spirit of invention (PCT Guidelines 5.30).